

Serial No. 10/662,081  
Amendment dated June 23, 2005  
Reply to Office Action of March 24, 2005

### REMARKS

In this paper, claims 1 and 3-5 are amended, claims 2 and 6 are canceled, and new claims 18-27 are presented. The title of the application has been amended, as has the abstract.

Claims 1, 3-5, 7-27 are pending, with claims 7-17 having been withdrawn as being directed to a non-elected species. Claims 1, 3-5 and 18-27 are being prosecuted.

### Species Election

The pending claims were divided into two supposedly distinct species:

Species A, drawn to Figures 2 and 31; and

Species B, drawn to Figure 1.

Applicants initially elected Species A, and confirm the election, in view of the comments below. Applicants, however, contend that the division, as indicated in the Office Action, is not proper, but that the proper division should be Figure 2 versus Figures 1 and 31.

Figure 2 illustrates a sensor having a working electrode 22 and a counter electrode 24 on a single surface or substrate. The two electrodes 22, 24 are coplanar as shown in Figure 2 and as described on page 5, lines 14-16 and page 40, line 16 of the specification.

Figure 1 illustrates a sensor having a working electrode 22 and a counter electrode 24 separated by a spacer layer 28. The two electrodes 22, 24 are facing electrodes; see page 5, lines 11-13 and page 38, lines 10-12.

Figure 31 (specifically, Figures 31A and 31B) provides a plan for providing individual working electrodes 1010 and the counter electrode 1020 on the substrate 1000. The working electrodes and the counter electrodes are formed on the web so that the sheet or web can be folded to superimpose the working and counter electrodes in a facing arrangement (page 50, lines 14-17).

This shows that Figure 2 is directed to a species having planar electrodes and that Figures 1 and 31 are directed to a species having facing electrodes. Thus, Applicants contend that the proper species division is:

Species A, drawn to Figure 2; and

Species B, drawn to Figures 1 and 31.

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Based on this understanding of the species division, Applicants contend that claims 1-6 (as amended herein), read on Species A, Figure 2. New claims 18-23 are dependent (either directly or indirectly) off of claim 1 and likewise read on Species A. New claims 24-27 are also directed to making a sensor having planar electrodes, which fall within Species A. Claims 7-17, directed to a sensor having facing electrodes, read on Species B, Figures 1 and 31.

### Abstract

The Abstract has been rewritten to be directed to the claimed invention. The Abstract now reads:

Methods for manufacturing electrochemical sensors are described. The sensors have a working electrode and a counter electrode, which are planar, and optionally an indicator electrode. The sensor includes a sample chamber to hold a sample of no more than 1  $\mu\text{L}$  in electrolytic contact with the working electrode. The methods provide sensors that can be used to determine the concentration of a biomolecule, such as glucose or lactate, in a biological fluid, such as blood or serum, using techniques such as coulometry, amperometry, and potentiometry.

### Title

The title of the application has been changed as suggested.

### 103 Rejections

Claims 1-4 and 6 were rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent No. 5,997,708 to Craig in view of U.S. Patent No. 5,496,453 to Uenoyama et al. Applicants disagree.

Claim 1 has been amended to clarify the steps in making the electrochemical sensor. Claim 1 now recites that a plurality of working electrodes and a plurality of counter electrodes are applied on a substrate (such as by printing, claims 18 and 19), and that the electrodes are overlaid with a second substrate. A sample chamber is created that has a volume of no more than 1  $\mu\text{L}$  (or no more than 0.5  $\mu\text{L}$ , claim 23). A spacer layer can be include (claim 3) from which can be removed a portion that forms the sample chamber (claims 21, 22). From the

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substrate, a plurality of electrochemical sensors are separated, so that each electrochemical sensor has at least one working electrode, at least one counter electrode, and at least one sample chamber region. Claim 24 is similar, but including the step of applying a plurality of indicator electrodes.

Craig discloses a method of manufacturing sensors by etching, or by similar processing, microstructures onto a substrate that is then folded. A spacer layer is provided between the microstructures so that the spacer layer separates the microstructures. Applicants contend that Craig does not disclose, at least, the microstructures being working electrodes and/or counter electrodes, applying the microstructures onto the substrate, a sample chamber volume of no greater than 1  $\mu\text{L}$ , and the microstructures being planar upon completion of the sensor. Craig is lacking in various additional claimed details.

Uenoyama et al. does not remedy the deficiencies of Craig. Although Uenoyama et al. provides a sensor with electrodes (2 and at surface 6) and a sample chamber (3'), there is no suggestion having the electrodes planar, as is recited in the pending claims, and having a sample chamber volume of no greater than 1  $\mu\text{L}$ .

At least for these reasons, Applicants contend that neither Craig, nor Uenoyama et al., nor their combination, render unpatentable the pending claims, as amended. Withdrawal of this rejection is requested.

#### Claim 5

Claim 5 was objected to as being dependent upon a rejected base claim. Applicants thank the Examiner for the indication of allowable subject matter of original claim 5. At this time, Applicants have elected to amend claim 1 (from which claim 5 depends) and to prosecute claim 1 and its dependent claims, as now amended. Applicants reserve the right to pursue original claim 5, rewritten in independent form to include all the limitations of the base claim and any intervening claims, in a continuation application.

#### Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution


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of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

MERCHANT & GOULD P.C.  
P.O. Box 2903  
Minneapolis, Minnesota 55402-0903  
(612) 332-5300

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Mara E. Liepa  
Reg. No. 40,066

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